

1 INTRAVENOUS CATHETER DEVICE

2 BACKGROUND OF THE INVENTION

3 1. Field of the Invention

4 The present invention relates to a device for the insertion of a flexible catheter into
5 a vein of a patient for intravenous administration of fluids. More Particularly the invention
6 relates to devices wherein the flexible catheter is inserted into the vein by a sharp needle
7 about which the catheter is snugly mounted, and the needle and catheter are inserted into
8 the vein and the needle retracted leaving the catheter in place. More particularly the
9 invention relates to a catheter insertion device wherein the insertion needle is retractable
10 into the device after removal. Most particularly the invention relates to a catheter insertion
11 device with an integral IV port wherein the insertion device is directly connected to the IV
12 fluid source.

13 2. Related Art

14 The development of flexible intravenous catheters has greatly increased the comfort
15 of patients during intravenous administration of medicinal fluids. The flexible catheter
16 prevents unwanted puncture of the vein. The flexible catheter normally consists of a
17 narrow tube of NYLON or TEFLON construction with a rigid member attached at the rear
18 end for connection to the source of fluid to be administered.

19 Because the catheter is flexible it cannot by itself be inserted into the vein.
20 Therefore, the catheter is snugly nested about a sharp hypodermic type needle which can
21 be inserted into the vein. After insertion the sharp needle is withdrawn leaving the catheter
22 in place for connection to the fluid source. The insertion needle is usually discarded as it
23 is intended for a single use only. Often the needle is discarded in a careless manner

leaving the exposed needle point as a hazard.

Accidental needle prick has been a problem for years in the health care industry.

However, the advent of the HIV or AIDS virus has focused attention on the problem. While several diseases, such as viral hepatitis, may be contracted from bodily fluids of infected persons, HIV has caused the most concern because to date no preventative or cure is known. Protection against accidental needle prick is expected to remain a concern even after a vaccine or cure is found, an ounce of prevention being worth a pound of cure.

Earlier U.S. patents 5,019,019 and 5,176,650 have addressed this problem in regard to catheter insertion devices.

SUMMARY OF THE INVENTION

To protect against accidental needle prick a catheter and insertion device are provided wherein the needle is retractable within the device after insertion of the catheter. The device comprises a hollow barrel or tube of semi-rigid plastic material into which the needle can be retracted after use. The insertion needle is mounted on a carrier with the sharp end oriented toward the insertion end of the barrel with the catheter snugly fit about the needle. A sliding tab is mounted to the carrier by an outwardly biased flexible member and extends through a longitudinal sliding track in the barrel. Near either end of the sliding track notches to engage locking hubs on the sliding tab to releasably lock the carrier in either the exposed or retracted position. The catheter and catheter carrier are secured to the needle carrier by a releasable latch that is released when the needle, needle carrier, catheter and catheter carrier are in the fully exposed position. A retainer ring holds the catheter carrier and catheter in position after retraction of the needle and needle carrier. The needle is retained inside the device during in use.

BRIEF DESCRIPTION OF THE DRAWING

Figure 1 shows the device ready for insertion into a vein with the hypodermic needle and catheter fully exposed.

Figure 2 shows the device in the fully retracted position.

Figure 3 shows the device after the catheter has been inserted and the hypodermic needle retracted.

Figure 4 is a side plan view of the device with the catheter and needle in the retracted position.

Figure 5 is a top plan view of the device with the catheter and needle in the retracted position.

Figure 6 is a cross sectional view taken along line 6-6 of Figure 4.

Figure 7 is a cross sectional view taken along line 7-7 of Figure 5.

Figure 8 is top plan view of the device with the catheter and needle in the exposed position.

Figure 9 is a cross sectional view of the device taken along line 9-9 of Figure 8.

Figure 10 is a cross sectional view of the device taken along line 10-10 of Figure 8.

Figure 11 is a cross sectional view taken along line 11-11 of Figure 10.

Figure 12 is a top plan view of the device with the catheter in the exposed position with the hypodermic needle retracted.

Figure 13 is a side plan view of the device with the catheter in the exposed position with the hypodermic needle retracted.

Figure 14 is a cross sectional view of the device taken along line 14-14 in Figure 12.

Figure 15 is a cross sectional view of the device taken along line 15-15 in Figure 12.

1 Figure 16 is an enlarged view of the area circled in Figure 15.

2 Figure 17 is a perspective exploded view of the device form the right side.

3 Figure 18 is a perspective exploded view of the device form the left side.

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5 DESCRIPTION OF THE PREFERRED EMBODIMENTS

6 For a detailed description of the preferred embodiment the reader is referred to the
7 appended figures in which like components are given like numerals for ease of reference.

8 For quick reference all of the reference numerals are listed in Table I below and their
9 corresponding parts identified with the figures in which the parts are identified. The parts
10 may be shown in other figures but are identified by the reference numerals in the listed
11 figures only.

12 Table I

| 13 Ref. No. | 14 Description | 15 Identified in Figure Number: |
|-----------------------|-----------------------------------|---|
| 16 1 | 17 protective sheath | 18 1-3, 6-7, 10-11, 16-18 |
| 19 2 | 20 port body | 21 1-3, 5, 9-11, 14-18 |
| 22 3 | 23 needle carrier | 24 1-3, 6-7, 9-11, 14, 17-18 |
| 25 4 | 26 catheter | 27 1, 3, 6-7, 9-10, 14, 16-18 |
| 28 5 | 29 IV tube | 30 1-3, 9, 14-15, 17-18 |
| 31 6 | 32 hypodermic needle | 33 1, 6-7, 9-10, 14, 16-18 |
| 34 7 | 35 catheter carrier | 36 1-3, 6, 10-11, 14, 16-18 |
| 37 8 | 38 needle locking tab | 39 1-3, 5, 9, 14, 17-18 |
| 40 9 | 41 needle locking slot | 42 1-4, 8-10, 14, 17, 18 |
| 43 9A | 44 needle locking slot | 45 1-4, 7-9, 17-18 |
| 46 10 | 47 needle carrier track | 48 1-3, 7-8, 10, 17-18 |
| 49 11 | 50 actuator | 51 4, 7, 9-10, 14, 17-18 |
| 52 12 | 53 flashback sight tube | 54 7-8, 10, 17-18 |
| 55 13 | 56 indicator | 57 7-8, 17-18 |
| 58 14 | 59 actuator spring | 60 7, 9-10, 17-18 |
| 61 15 | 62 rear retainer ring | 63 7, 10-11, 14, 18 |
| 64 16 | 65 flow cavity | 66 7, 9, 15-16 |
| 67 17 | 68 catheter retainer | 69 7, 10, 14, 17-18 |
| | slot | |

| | | | |
|----|----|----------------------|-----------------------|
| 1 | 18 | membrane | 6-7, 9-10, 14, 16, 18 |
| 2 | 19 | needle carrier slot | 18 |
| 3 | 20 | catheter taper | 7, 9, 18 |
| 4 | 21 | catheter carrier | |
| 5 | | retainer ring | 7, 10, 14, 17-18 |
| 6 | 22 | retainer ring relief | |
| 7 | | slot | 7, 17-18 |
| 8 | 23 | flashback blood path | 7, 10 |
| 9 | 24 | needle retainer | |
| 10 | | notch | 9 |
| 11 | 25 | membrane aperture | 16 |
| 12 | 26 | forward retainer | |
| 13 | | spring | 6, 11, 17-18 |
| 14 | 27 | forward locking | |
| 15 | | surface | 6, 11, 17-18 |
| 16 | 28 | needle carrier | |
| 17 | | release tab | 6-7, 11 |
| 18 | 29 | needle carrier | |
| 19 | | release ramp | 6, 11 |
| 20 | 30 | forward catheter | |
| 21 | | locking surface | 6, 11 |
| 22 | 31 | conical ramp | 7, 10-11, 18 |
| 23 | 32 | IV liquid flow path | 16 |
| 24 | 33 | rear retainer slot | 14 |
| 25 | 34 | port body retainer | |
| 26 | | surface | 16, 18 |
| 27 | 35 | locking ramp | 16, 18 |
| 28 | | | |

29 Referring first to Figures 17 and 18 the components of the catheter device are seen

30 in exploded views. The device is seen to comprise a protective sheath 1 having a
 31 longitudinal slot or needle carrier track 10 on one surface with needle locking slots 9 and
 32 9A near either end of the carrier track 10. The catheter is seen to have a near quarter
 33 round cross sectional or tear drop area with the needle and catheter in the largest area
 34 and adjacent the flat for ease of use and insertion of the needle and catheter (this can best
 35 be seen by looking at the internal parts which conform to the cross sectional area of the
 36 sheath such as membrane 18 and port body retaining surface). A catheter retaining ring
 37 21 and retaining ring slot 22 are located at the proximal end along with an aperture through

1 which the hypodermic needle and catheter may be exposed. The catheter 4 and catheter
2 carrier 7 are mounted on the needle carrier 3 with membrane 18 between the two. As
3 assembled for shipment the hypodermic pierces the membrane 18 and fits into the catheter
4 4. On top of the needle carrier 3 is actuator 11 which is connected to the needle carrier
5 3 by actuator spring 14. On either side of actuator 11 are needle locking tabs 8 which may
6 engage needle locking slots 9 and 9A. At the rear of the needle carrier 3 is flashback sight
7 tube 12 which contains flashback indicator 13. located alongside needle carrier 3 is port
8 body 2 having flow cavity 16 which is aligned with membrane aperture 25. The IV fluid
9 tube 5 is connected to the port body.

10 Referring now to the Figure 1 the device is shown in perspective view in the ready
11 mode with the catheter 4, catheter carrier 7 and hypodermic needle 6 fully extended from
12 the sheath 1 with the hypodermic needle 6 locked into this position by the needle locking
13 tab 8 engaging the needle locking slot 9A. The IV tube 5 is shown connected to the port
14 body 2. The needle carrier 3 is shown extending through the needle carrier track 10.

15 In Figure 2 the device is shown in the stowed mode as for shipment with the
16 catheter and needle fully retracted into the sheath 1 and the hypodermic needle locked into
17 position by the needle locking tab 8 engaged in the needle locking slot 9. The catheter is
18 fixed in a locked and stowed position by the catheter carrier 7.

19 Figure 3 shows the device as it would be used delivering IV fluids to a patient with
20 the catheter 4 fully extended and the hypodermic needle retracted into the sheath 1. The
21 hypodermic needle is locked into the retracted position by the needle locking tab 8
22 engaged in the needle locking slot 9.

23 Referring now to Figures 4-7 details of the needle, needle carrier, catheter and

1 catheter carrier in the stowed position carrier are shown. Figures 4 and 5 are plan views
2 shown to provide an orientation basis for figures 6 and 7 which are cross sectional views.
3 In Figure 7 the needle 6 and catheter 4 are placed in the stowed and safe position by
4 sliding them longitudinally in the inner cavity of the protective sheath 1 to a position where
5 the needle 6 and catheter 4 cannot be touched. The hypodermic needle 6 is securely
6 fastened to the needle carrier 3 which is locked into position by actuator spring 14 applying
7 pressure to needle locking tab 8 (Figure 5) to needle locking slot 9 (Figure 4), thereby
8 preventing any further longitudinal movement. The spring 14 must be strong enough to
9 bias the tab into the slot, otherwise a coiled spring (not shown) may be placed beneath the
10 spring 14 to add force to bias the tab into the slot.

11 As shown in Figure 6 the catheter 4 is securely fastened to the catheter carrier 7.
12 The catheter carrier 7 is connected to the needle carrier 3 by the forward retainer spring
13 26 on the needle carrier 3 engaging an interference fit between the forward locking surface
14 27 on the forward retainer spring 26 and the catheter locking surface 30 on the catheter
15 carrier 7.

16 Referring now to Figures 8-11 details of the needle, needle carrier, catheter and
17 catheter carrier in the exposed position are shown. As shown in Figure 8 the hypodermic
18 needle 6 and catheter 7 are moved to the fully extended position along with port body 2 by
19 depressing actuator 11 against the force of the actuator spring 14 to disengage the needle
20 locking tab 8 (figure 9) from the needle locking slot 9 allowing the needle carrier 3 and the
21 catheter carrier 7 to slide longitudinally within the confines of the needle carrier track 10
22 (Figure 10) and in the inner cavity of the protective sheath 1, to a position where the needle
23 locking tab 8 can engage and lock the forward needle locking slot 9A.

1 Referring now to Figure 10, the conical ramp 31 located on catheter carrier 7
2 deforms the molded shape of the protective sheath 1, relieved by, as best shown in Figure
3 17, the retainer ring relief slot 22, to allow the catheter retainer slot 17, a molded feature
4 of the catheter carrier 7, to lock into the carrier retainer ring 21, a molded feature of the
5 protective sheath 1. In this longitudinally locked exposed position the hypodermic needle
6 and catheter can pierce a vein and start an IV injection. The catheter 4 has catheter
7 taper 20 to allow a less painful insertion into the vein. As an indication that a vein has
8 been entered, blood under pressure flows through the hypodermic needle 6 along the
9 flashback blood path 23 and is absorbed in an absorbent indicator 13 located in the
10 flashback sight tube 12. The flashback sight tube 12 is molded from clear plastic and can
11 be viewed through the opening in the needle carrier track 10 as shown in Figure 8.

12 With the hypodermic needle 6 in the extended position no IV fluid can flow due to
13 the close fit between the hypodermic needle 6 and the catheter 4. This allows the IV fluids
14 to be connected to the device before a vein is pierced. Air can be purged from the system
15 prior to the application of the IV needle.

16 Referring now to Figure 11 when the needle carrier 3 and the catheter carrier 7 is
17 in the fully extended and locked position, the forward retainer spring 26 slides onto the
18 needle carrier release ramp 29 located on the needle carrier release tab 28, a molded
19 feature of the protective sheath 1, and disengages the forward locking surface 27 from the
20 forward catheter locking surface 30. This allows the needle carrier 3 to be retracted
21 separately from the catheter carrier 7. The catheter carrier 7 and the catheter 4 remain
22 locked, extended and in the vein.

23 Referring now to Figures 12-16 the operation of the device with the needle in the

1 retracted position is shown. The hypodermic needle 6 is moved to the fully retracted
2 position by depressing actuator 11 against the force of the actuator spring 14 to disengage
3 the needle locking tab 8 from the needle locking slot 9A allowing the needle carrier 3 to
4 slide longitudinally constrained by the needle carrier track 10 and in the inner cavity of the
5 protective sheath 1 to a position where the needle locking tab 8 can engage needle locking
6 slot 9. The rear retainer tab 15 located on the needle carrier 3 snaps into the rear retainer
7 slot 33 located on the port body 2. The needle carrier 3 is retained by this patient tamper
8 proof mechanism formed by the rear retainer tab 15 and rear retainer slot 33.

9 With the needle carrier 3 and the hypodermic needle 6 in the retracted position and
10 the catheter in the extended position, the hypodermic needle 6 no longer passes through
11 the membrane 18. This membrane, made from an elastomer, allows an elastic aperture,
12 formed by the initial hypodermic needle 6 penetration, to close.

13 Referring now to Figures 15 and 16 the membrane 18 forms a seal as the
14 hypodermic needle 6 is removed and also forms a compressed gasket seal between the
15 catheter carrier 7 and the port body 2. This seal is maintained by the locking ramp 35 on
16 opposing sides of the port body 2 coming into contact with the port body retainer surface
17 34., creating a snap interference fit to compress membrane 18 at the contact surfaces.

18 When the hypodermic needle 6 is in the retracted position the IV fluids are free to
19 flow in the flow cavity 16 along flow path 32, through the IV tube 5, through the port body
20 2, through membrane aperture 25 (best seen on Figure 18) through catheter carrier 7 and
21 catheter 4 to the vein.